PCT/DK 2004/000516

PA 1183201

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

June 18, 2004

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE UNDER 35 USC 111.

APPLICATION NUMBER: ***60/496,112***
FILING DATE: ***August 19, 2003***

PRIORITY DOCUMENT
SUBMITTED OR TRANSMITTED IN
COMPLIANCE WITH
RULE 17.1(a) OR (b)

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS

T. WALLACE
Certifying Officer

PATENT APPLICATION SERIAL NO. _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

08/20/2003 MBERHE 00000038 141447 60496112
01 FC:1005 160.00 DA

PTO-1556
(5/87)

*U.S. Government Printing Office: 2001 — 481-697/59173

Attorney Docket No.: 6710.003-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

FILING UNDER 37 C.F.R. §1.53(c)

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Express Mail Label No. EV 246878775 US
Date of Deposit August 14, 2003

Sir:

This is a request for filing a provisional application under 37 C.F.R. §1.53(c), of the inventors:

Jim Radmer, a citizen of Denmark, residing at Asmundshoj 443, DK-3480 Fredensborg, Denmark; and

Erik Winkel Ethelfeld, a citizen of Denmark, residing at Frederiksborggade 42, 3.tv., DK-1360 Copenhagen K, Denmark

for application entitled: Needle Device With Retraction Means.

The provisional application contains:

25 pages of specification 1 page of abstract

9 sheets of drawings

Address all future communications to Reza Green, Esq., Novo Nordisk Pharmaceuticals, Inc., 100 College Road West, Princeton, NJ 08540.

Please charge the required fee, estimated to be $160, with this application and to credit any overpayments to Novo Nordisk Pharmaceuticals, Inc., Deposit Account No. 14-1447. Please charge any additional fees, should they be required, to Deposit Account No. 14-1447. A duplicate of this sheet is enclosed.

Respectfully submitted,

Date: August 19, 2003

Marc A. Began, Reg. No. 48,829
Novo Nordisk Pharmaceuticals, Inc.
100 College Road West
Princeton, NJ 08540
(609) 987-5800

23650
PATENT TRADEMARK OFFICE

Attorney Docket No.: 6710.003-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

EXPRESS MAIL CERTIFICATE

Mail Stop Provisional Patent Application
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Re: U.S. Provisional Application for
"Needle Device With Retraction Means"
Applicants: Radmer et. al

Sir:

Express Mail Label No. EV 246878775 US

Date of Deposit August 19, 2003

I hereby certify that the following attached paper(s) or fee

1. Filing Under 37 C.F.R. §1.53(c) (in duplicate)
2. Provisional Application (25 pages of specification, 1 page of abstract and 9 sheets of drawings)

are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Rashida Haji
(Name of person mailing paper(s) or fee)

Rashida Haji
(Signature of person mailing paper(s) or fee)

Mailing Address:
Novo Nordisk Pharmaceuticals, Inc.
100 College Road West
Princeton, NJ 08540
(609) 987-5800

23650
PATENT TRADEMARK OFFICE

NEEDLE DEVICE WITH RETRACTION MEANS

The present invention generally relates to needles or needle-like members adapted for insertion at a selected site within the body of a subject for subcutaneous, intravenous, intramuscular or intradermal placement, the needle being carried by a device comprising a lower surface adapted for application towards the skin of a subject. In specific embodiments, the invention relates to infusion needles for the infusion of a drug, or to needle-formed sensors.

BACKGROUND OF THE INVENTION

In the disclosure of the present invention reference is mostly made to the treatment of diabetes by injection or infusion of insulin, however, this is only an exemplary use of the present invention.

Portable drug delivery devices for delivering a drug to a patient are well known and generally comprise a reservoir adapted to contain a liquid drug and having an outlet in fluid communication with a hollow infusion needle, as well as expelling means for expelling a drug out of the reservoir and through the skin of the subject via the hollow needle. Such devices are often termed infusion pumps.

Basically, infusion pumps can be divided into two classes. The first class comprises relatively expensive infusion pumps intended for 3-4 years use, for which reason the initial cost for such a pump often is a barrier to this type of therapy. Although more complex than traditional syringes and pens, the pump offer the advantages of continuous infusion of insulin, precision in dosing and optionally programmable delivery profiles and user actuated bolus infusions in connections with meals.

Addressing the above problem, several attempts have been made to provide a second class of drug infusion devices that are low in cost and convenient to use. Some of these devices are intended to be partially or entirely disposable and may provide many of the advantages associated with an infusion pump without the attendant cost and inconveniencies, e.g. the pump may be prefilled thus avoiding the need for filling or refilling a drug reservoir. Examples of this type of infusion devices are known from US patents 4,340,048 and 4,552,561 (based on osmotic pumps), US patent 5,858,001 (based on a piston pump), US patent 6,280,148 (based on a membrane pump), US patent 5,957,895 (based on a flow restrictor pump (also know as a bleeding hole pump), US patent 5,527,288 (based on a gas generat-

ing pump), or US patent 5,814,020 (based on a swellable gel) which all in the last decades have been proposed for use in inexpensive, primarily disposable drug infusion devices, the cited documents being incorporated by reference.

The disposable pumps generally comprises a skin-contacting mounting surface adapted for application to the skin of a subject by adhesive means, and with the infusion needle arranged such that in a situation of use it projects from the mounting surface to thereby penetrate the skin of the subject, whereby the place where the needle penetrates the skin is covered while the appliance is in use.

The infusion needle may be arranged to permanently project from the mounting surface such that the needle is inserted simultaneously with the application of the infusion pump. Examples of this configuration can be found in US patents 2,605,765, 4,340,048 and in EP 1 177 802. Although this configuration provides a simple and cost-effective solution, the actual user-performed piercing of the tissue with the needle is often problematic as people who are not experts in medicine are usually insufficiently practised to place such a needle correctly and they often suffer from a fear of the likely pain. Although not relating specifically to infusion pumps, US patent 5,851,197 discloses an injector in which an infusion set comprising a skin-mountable surface with a protruding needle can be mounted, the injector upon actuation driving the entire infusion set into contact with a skin portion whereby the needle is inserted through the skin.

Addressing the above problem, infusion pump devices have been proposed in which the pump device is supplied to the user with the needle in a retracted state, i.e. with the distal pointed end of the needle "hidden" inside the pump device, this allowing the user to place the pump device on the skin without the possibility of observing the needle. When first the needle is hidden, at least some of the fear is overcome making the introduction of the needle in a second step less problematic. US patents 5,858,001 and 5,814,020 disclose infusion devices of this type in which an infusion needle is arranged in an upper housing portion pivotably arranged relative to a base plate portion. In this way the user can introduce the needle by pressing the upper portion into engagement with the base plate portion.

To further reduce the fear and pain associated with the introduction of the needle, many recent pump devices have been provided with actuatable needle insertion means, which just has to be released by the user after which e.g. spring means quickly will advance the needle through the skin.

For example, US patent 5,957,895 discloses a liquid drug delivery device comprising a bent injection needle which is adapted to project through a needle aperture in the bottom surface of the housing in a situation of use. A movable needle carrier is disposed in the housing for carrying the injection needle and for causing the injection end of the needle to project through the needle aperture upon movement of the needle carrier.

US patent 5,931,814 discloses an infusion device having a housing with a drug reservoir, an infusion needle (or cannula) communicating with the reservoir, means for inserting the needle, and pump means for discharging the reservoir contents through the needle. The needle is fixed relative to the housing and projects beyond the lower skin-contacting surface of the housing to the depth required for injection. The needle is surrounded by a protective element which is moved by spring means from a first end position in which the protective device projects beyond the lower surface of the housing and beyond the needle to a second end position in which the protective device does not project beyond the underside of the casing. An advantage of this design is that the needle is arranged in a fixed position relative to the reservoir. WO 02/15965 discloses a similar infusion device in which a base plate member acts as a protecting element until an upper part of the device, to which the needle is fixed, is moved down into engagement with the base plate member.

In the devices disclosed in US patents 5,957,895 and 5,931,814 the needle is automatically inserted by the release of pre-tensioned spring means arranged within the devices, whereas in the device known from WO 02/15965 the needle is inserted by the user actively moving the hidden needle.

By providing needles which can be inserted after the device has been applied to skin of the user, the risk of needle injuries prior to insertion is reduced, just as the user is not visually confronted with the needle. However, when the device is to be removed from the skin of the user the same problems appear again, i.e. the used needle projecting from the lower surface of the device represents a risk of injury just as the user is visually confronted with the needle. In fact, the risk of serious injuries is considerably higher as the used needle has been exposed to the patient's blood or body fluids, this especially presenting a risk to other persons than the user such as health care personal.

Addressing this problem, WO 02/02165 discloses a needle device having a needle retraction mechanism that retracts the needle upon removing the device from the skin surface. In this

device the mechanism "senses" when a portion of the device has been removed from the skin surface. US patent 5,931,814 discloses a dermally affixed injection device in which a protective element can be moved to cover the needle, the protective element being actuatable before or after the device has been removed from the skin surface of the user.

Before turning to the disclosure of the present invention, a different type of device relying on the insertion of a needle or needle-like structure will be described.

Although drug infusion pumps, either disposable or durable, may provide convenience of use and improved treatment control, it has long been an object to provide a drug infusion system for the treatment of e.g. diabetes which would rely on closed loop control, i.e. being more or less fully automatic, such a system being based on the measurement of a value indicative of the condition treated, e.g. the blood glucose level in case of insulin treatment of diabetes.

A given monitor system for measuring the concentration of a given substance may be based on invasive or non-invasive measuring principles. An example of the latter would be a non-invasive glucose monitor arranged on the skin surface of a patient and using near-IR spectroscopy, however, the present invention is concerned with the introduction of a transcutaneous device such as a needle-formed sensor element.

The sensor may be placed subcutaneously being connected to external equipment by wiring or the substance (e.g. fluid) to be analysed may be transported to an external sensor element, both arrangements requiring the placement of a subcutaneous component (e.g. small catheter or tubing), the present invention addressing both arrangements. However, for simplicity the term "sensor" is used in the following for both types of elements introduced into the subject.

Turning to the sensor elements *per se*, relatively small and flexible electrochemical sensors have been developed for subcutaneous placement of sensor electrodes in direct contact with patient blood or other extra-cellular fluid (see for example US patent 5,482,473), wherein such sensors can be used to obtain periodic or continuous readings over a period of time. Insertion devices for this type of sensors are described in, among others, US patents 5,390,671, 5,391,950, 5,568,806 and 5,954,643 which hereby are incorporated by reference.

More specifically, US patent 5,954,643 discloses an insertion set comprising a mounting base supporting a proximal end of a flexible thin film sensor, the sensor including a distal

segment with sensor electrodes thereon which protrudes from the mounting base for transcutaneous placement, wherein the sensor distal segment is slidably carried by a slotted insertion needle fitted through the assembled base. Placement of the insertion set against the patient's skin causes the insertion needle to pierce the skin to carry the sensor electrodes to the desired subcutaneous site, after which the insertion needle can be slidably withdrawn from the insertion set. A similar arrangement is known from US patent 5,568,806.

DISCLOSURE OF THE INVENTION

Having regard to the above-identified problems, it is an object of the present invention to provide a needle device comprising needle retraction means which is easy to use and provide a high degree of safety against needle injuries. The device should allow for easy and swift, automatic needle retraction, yet being reliable and convenient in use. The device should be compact in size and be designed for cost effective manufacturing.

Correspondingly, a needle device is provided, comprising a lower surface adapted for application towards the skin of a subject, attaching means for securing the lower surface relative to the skin, and a needle having a pointed end adapted to penetrate the skin of the subject. The needle is mounted for movement between an extended position in which the needle projects relative to the lower surface and a retracted position in which the needle is retracted relative to the lower surface. The needle device further comprises release means operatable from a first condition through an intermediate condition to a second condition, whereby operation of the release means from the first to the intermediate condition causes the needle to be moved from the extended position to the retracted position, and operation of the release means from the intermediate to the second condition causes release of the attaching means.

The lower surface may be a mounting surface adapted for application against the skin of a subject (e.g. user or patient). The mounting surface may be held in contact with the skin by attaching means external to the mounting surface (e.g. coupling means allowing the needle device to be coupled to a skin mountable device, or an adhesive bandage) or by adhesive means provided on the mounting surface. The lower surface may also be adapted for mounting towards the skin via an interposed component of a skin mountable device, e.g. a skin mountable device may comprise a receiving portion to which the needle device is attached, the needle being inserted into the skin through an aperture in the receiving portion.

In case adhesive means is provided on the mounting surface, the release means may comprise gripping means connected to a peripheral portion of the mounting surface, whereby operation of the gripping means from a first to an intermediate condition causes the needle to be moved from the extended position to the retracted position, and operation of the gripping means from the intermediate to the second condition causes the mounting surface to be pulled off the skin of the subject. As appears, whereas needle retraction may be considered an "action" which may take place in a fraction of a second, the removal (i.e. pulling off) of the adhesive mounting surface from the skin may be characterized as a "process", correspondingly, the period of time when operating the release means from the intermediate to the second condition may be somewhat longer than operating the release means from the first to the intermediate condition.

In exemplary embodiments the release means comprises needle retraction means operatable between a first position in which the needle projects relative to the lower surface and a second position in which the needle is retracted relative to the lower surface, the needle retraction means being moved between its first and second positions when the gripping means is operated from the first to the intermediate condition. In this way the movement of the needle is not necessarily directly linked to the actual movement of gripping means, e.g. the gripping means may be used to release a pre-tensioned retraction mechanism. Further, the needle retraction means may be operatable connected to the gripping means by an intermediate member allowing movement of the gripping means to be transferred to the needle retraction member, e.g. by a pulling string or strip of material.

In exemplary embodiments attaching means comprises a sheet member having an upper surface connected to the lower surface of the needle device, and a lower adhesive surface, the gripping means being connected to the sheet member, advantageously in the form of a tab formed integrally with the sheet member. To protect the needle device against accidental removal (e.g. during sleep or exercise) the sheet member advantageously extends from the periphery of the mounting surface. The sheet member may be of any suitable material, e.g. woven or non-woven medical grade materials normally used for this purpose.

The needle device may be delivered to the user in an initial condition with the needle extending from the lower surface, such that the needle is introduced through the skin as the needle device is mounted relative to the skin surface, however, in exemplary embodiments the needle is mounted for movement between an initial position in which the needle is retracted relative to the lower surface and the extended position in which the needle projects relative to the

lower surface. To prevent re-use of the needle, the needle device may comprise locking means for locking the needle in the retracted position after a single reciprocation of the needle from the initial position to the extended position and to the retracted position.

As mentioned above, the needle device of the present invention may comprise needles of different types. For example, the needle may be a hollow needle or cannula for the infusion of a drug, or the needle may be in the form of a needle-formed sensor. The needle device may be in the form of an infusion set comprising a fluid conduit adapted for connection to a drug delivery device or adapted for connection to such a fluid conduit.

The needle device may also be in the form of a drug delivery device, further comprising a housing providing the lower surface, a reservoir adapted to contain a liquid drug and comprising an outlet means allowing the needle to be arranged in fluid communication with an interior of the reservoir, and expelling means for, in a situation of use, expelling a drug out of the reservoir and through the skin of the subject via the needle.

The above-described drug delivery device may also be provided as two units, e.g. a needle unit (or needle device) as disclosed above, in combination with a pump unit, the pump unit comprising a mounting surface adapted for application against the skin of a subject, a reservoir adapted to contain a liquid drug and comprising an outlet means allowing the needle to be arranged in fluid communication with an interior of the reservoir, and expelling means for, in a situation of use, expelling a drug out of the reservoir and through the skin of the subject via the pointed end. The attaching means is adapted for securing the needle unit to the pump unit and thereby relative to the skin of the subject. In such a combination operation of the release means from the first to the intermediate condition causes the needle to be moved from the extended position to the retracted position, and operation of the release means from the intermediate to the second condition causes release of needle device from the pump unit.

The above concept can be regarded as a modular system providing a number of advantages. For example, a given pump unit (either a prefilled pump or a pump adapted to be filled by the user) may be used a number of times with a new needle device. Further, both the pump unit and the needle unit may be supplied in a number of variants, e.g. different types of prefilled pumps containing different amounts of different drugs, or different types of needles having different lengths. The needle unit may also be in the form of a needle sensor and the "pump unit" may correspondingly be in the form of a device adapted to transmit and/or process data acquired via the sensor.

In exemplary embodiments a receiving portion of the pump unit and a corresponding portion of the needle device comprise releasable coupling means allowing the needle unit to be secured to and released from the pump unit, the coupling means preferably being of mechanical, interlocking nature.

As for the above-disclosed "unitary" needle device, the needle may be mounted for movement between an initial position in which the needle is retracted relative to the lower surface and the extended position in which the needle projects relative to the lower surface. Advantageously, the needle is moved from its initial to its extended position when the needle unit is secured to the pump unit. Also, the needle unit may comprise locking means for locking the needle in the retracted position after a single reciprocation of the needle from the initial position to the extended position and to the retracted position, thereby helping to prevent accidental needle injuries as well as reuse of the needle.

For all of the above embodiments in which a fluid communication is established between a needle and a reservoir, this may be provided either via a direct connection between the needle and the reservoir (e.g. by penetrating a septum of the reservoir) or indirectly (e.g. via connection to a structure in flow communication with the reservoir, e.g. the outlet of a suction pump drawing drug from a reservoir).

In order to provide a skin mountable medical device, e.g. of the above-discussed types, with an extended operational life, the medical device may be attached to a base plate unit comprising a mounting surface with means having an adhesive surface, the medical device and the base plate unit comprising mating, releasable coupling means allowing the medical device to be secured to the base plate unit a given number of times. The medical device may be a unitary drug delivery device or a unitary sensor device, or it may be a modular device comprising e.g. a pump unit and a needle unit or a sensor unit and a skin-penetrating sensor needle.

To extend the operational life of a medical device comprising an adhesive mounting surface, it may be provided with a first peelable sheet having an upper surface and an adhesive lower surface, the upper surface being adapted for peelable attachment to the adhesive surface of the mounting surface. Advantageously, at least one further peelable sheet is provided, each further peelable sheet comprising an upper surface and an adhesive lower surface, the first and the further peelable sheets being arranged in a stacked arrangement with their respec-

tive upper surfaces attached to the overlying adhesive surface. Indeed, such a stack may be used in combination either with a skin mountable medical device comprising an adhesive mounting surface or in combination with a base plate unit as described above.

As used herein, the term "drug" is meant to encompass any drug-containing flowable medicine capable of being passed through a delivery means such as a hollow needle in a controlled manner, such as a liquid, solution, gel or fine suspension. Representative drugs include pharmaceuticals such as peptides, proteins, and hormones, biologically derived or active agents, hormonal and gene based agents, nutritional formulas and other substances in both solid (dispensed) or liquid form. Correspondingly, the term "subcutaneous infusion" is meant to encompass any method in which a needle device is inserted at a selected site within the body of a patient for subcutaneous, intravenous, intramuscular or intradermal delivery of a drug to a subject. Further, the term needle or needle device (when not otherwise specified) defines a piercing member (including an array of micro needles) adapted to be introduced into or through the skin of a subject.

BRIEF DESCRIPTION OF THE DRAWINGS

In the following the invention will be further described with references to the drawings, wherein

figs. 1A and 1B show in perspective views situations of use for a first embodiment of a drug delivery device,

fig. 2A shows a needle unit,

fig. 2B shows an exploded view of the needle unit of fig. 2A,

figs. 3A and 3B show cross-sectionals view of the needle unit fig. 2A mounted to a drug delivery device as shown in fig. 1A,

figs. 4A and 4B show in perspective partially cut-away views delivery devices corresponding to figs. 1A and 1B,

figs. 5A and 5B show in perspective views situations of use a further embodiment of a drug delivery device,

figs. 5C and 5D show in perspective views further embodiments of a drug delivery device,

fig. 6 shows an embodiment of a needle subunit, and

figs. 7A-7E show different expelling means suitable for use with drug delivery devices.

In the figures like structures are identified by like reference numerals.

DESCRIPTION OF EXEMPLARY EMBODIMENTS

When in the following terms as "upper" and "lower", "right" and "left", "horizontal" and "vertical" or similar relative expressions are used, these only refer to the appended figures and not to an actual situation of use. The shown figures are schematic representations for which reason the configuration of the different structures as well as there relative dimensions are intended to serve illustrative purposes only.

Fig. 1A shows a perspective view of medical device in the form of a drug delivery device in accordance with aspects of the invention. More specifically, fig. 1A shows a drug delivery device 250 arranged on a skin surface of user and in a situation of use just prior to the user removing the device from the skin. The drug delivery device comprises a housing 201 with a lower surface attached to an upper surface 271 of a flexible sheet (or patch) 270, the sheet comprising a lower adhesive surface allowing the device to be mounted on a skin surface of a user as shown. When supplied to the user, the adhesive surface is advantageously covered with a peelable release liner. The device further comprises a drug reservoir, a subcutaneous needle as well as expelling means (see below) for expelling the drug from the reservoir to the user via the subcutaneously arranged needle. The needle is arranged in a needle unit having a carrier 230 pivotally connected to the housing. Corresponding to the situation shown in fig. 1A the needle is in an extended position with its pointed needle end inserted subcutaneously in the user. To protect the delivery device against accidental removal (e.g. during sleep or exercise) the sheet and its lower adhesive surface 272 is somewhat larger than the lower surface of the housing, the sheet thereby providing a border 273 around the device. The sheet also comprises a tab member 275 formed integrally with sheet. The tab is relative long allowing it to be folded in a zigzag configuration upon the border with only a short gripping portion 276 extending from the border, the gripping portion allowing the tab to be gripped by the use as shown.

When the user intends to remove the delivery device from the skin surface, the user grips the gripping portion of the tab and pulls it in a first direction substantially in parallel with the skin surface, by which action the zigzag folded tab unfolds to its full length as shown in fig. 1B. As also shown a pulling member in the form of a flexible strip 277 is attached at one end to the tab and at another end to a needle retraction member (see below) arranged within the housing, the pulling member extending through an opening 278 in the housing. As the tab is unfolded the pulling member is moved and the thereto attached retraction member pivots (or releases) the needle unit from an extended position in which the needle projects relative to the lower surface to a retracted position in which the needle is retracted relative to the lower surface, this as indicated by the carrier 230 being moved to a position in which it projects relative to the housing. When the needle has been withdrawn from the skin, the user uses the now unfolded tab to pull off the entire delivery device from the skin surface, for example by pulling the tab in a direction away from the skin surface (not shown).

As appears from the above, release means in the form of the tab has been operated from a first initial condition (corresponding to fig. 1A) through an intermediate condition (corresponding to fig. 1B) to a second condition (not shown), whereby operation of the release means from the first to the intermediate condition has caused the needle to be moved from an extended position to a retracted position, and operation of the release means from the intermediate to the second condition has caused release of the attaching means in the form of the adhesive sheet from the skin surface.

As illustrated, the tab is moved in a first direction in parallel with the skin surface, however, as the strip 277 is flexible, the user may operate the tab also between the first and intermediate positions by pulling in a direction away from the skin surface, e.g. perpendicularly.

Before turning to the description of the retraction mechanism, the needle unit 200 as shown in figs. 2A and 2B will be described. More specifically, fig. 2A shows a needle unit 200 comprising a needle carrier 230 to which a U-formed needle 210 and a cover member 220 are attached. The needle comprises a first needle portion 213 having a first pointed end adapted to penetrate the skin of a subject, and a second needle portion 214 in fluid communication with the first needle portion via an intermediate needle portion 215 and having a second pointed end, the two needle portion being arranged substantially in parallel with each other corresponding to the legs of the U-formed needle. The carrier comprises gripping means 231, 232 for holding the needle, hinge means 233 allowing the needle unit to be pivotally

connected to a delivery device, and first and second hook members 236, 235 intended for engagement with the delivery device (see below).

The cover member is made from a deformable elastic or non-elastic material and comprises first and second collapsible cover portions 221, 222 encapsulating the first respectively the second needle portions, the cover portions being collapsible from an initial configuration surrounding the needle portions to a collapsed configuration (e.g. in the form of an elastic rubber cover as shown or a telescoping arrangement) wherein the needle portions extend through the cover portions (see below). In the shown embodiment the cover portions are in the form of a bellows and a rounded cylinder, however, they may have any configuration allowing them to collapse. The two cover portions are connected by an intermediate portion 225 which in combination with the carrier forms a conduit providing fluid communication between the first and second enclosures formed by the two cover portions, the intermediate portion comprising a window 226 closed by a paper sheet 227. The paper sheet is penetratable to sterilizing gases (e.g. water vapour or ethylene gas) yet provides a sterility barrier for the encapsulated, this allowing sterilization of the enclosed needle.

Although not essential for the present invention, the needle may be mounted for movement between an initial position in which the needle is retracted relative to the lower surface allowing the delivery device to be handled and mounted on a skin surface without the needle projecting from the lower surface thereof, and an extended position in which the needle projects relative to the lower surface thus allowing a drug to be delivered, this as corresponding to the fig. 1A situation.

Correspondingly, figs. 3A and 3B show partial cross-sectionals view of the needle unit 200 incorporated in the drug delivery device 250. For illustrative purposes, the sheet member 270 is not shown. The drug delivery device comprises a base plate 251 with a lower skin mountable surface 252 and an aperture 253, a housing member 255 forming a secondary reservoir 256 containing a drive fluid (see description of the fig. 7D embodiment below) and in which a flexible, bag-like drug reservoir 260 is arranged, the drug reservoir comprising a needle-penetratable elastomeric septum 261. The needle unit is pivotally connected to the housing member corresponding to a hinge 234, the carrier 230 thereby forming a lid member. In the shown embodiment the lid member is part of a relatively small needle unit, however, the lid may also be formed integrally with the housing member, the two portions being connected by e.g. a film hinge, in which case the needle unit would incorporate a portion of the drug delivery device.

Fig. 3A shows the delivery device in an initial state in which both of the needle portions 213, 214 are sterilely enclosed within the collapsible cover portions 221, 222. Fig. 3B shows the delivery in a state of use in which the lid has been moved into locking engagement with the needle retraction member by means of the hook member 236 (see below). During this operation the first needle portions is moved through the aperture in the base plate, thereby penetrating the skin of the user when the delivery device has been mounted on a skin surface, and the second needle portion penetrates the reservoir septum to thereby establish fluid communication between the reservoir and the needle. As appears from the figure, during this operation the cover portions 221, 222 collapses as they are moved into engagement with the base plate respectively the septum, the pointed needle portions thereby penetrating the covers. After use the movement of the needle unit is reversed to thereby withdraw the used needle into the device and de-connect the needle from the reservoir to thereby stop the flow and/or prevent leakage.

Figs. 4A and 4B show the delivery device 250 in the same situations of use as shown in figs. 1A and 1B respectively, the figures showing the retraction member 280 and its relationship with the needle unit 200 and the pulling member 277 and tab 275. More specifically, the needle retraction member is operatable between a first position in which the needle projects relative to the lower surface and a second position in which the needle is retracted relative to the lower surface, wherein the needle retraction member is moved between its first and second positions when the tab and the pulling member is operated between the first and intermediate conditions as described above.

The needle retraction member is attached to the pulling member 277 and comprises a first hook member 281 adapted to engage the first hook member 236 on the needle unit when the latter is moved from its initial position to its extended position (see fig. 4A), an upwardly sloping ramp surface 282 and a flexible arm with a second hook member 283. When the user operates the tab from its initial folded configuration to its extended configuration (see fig. 4A) the pulling member moves the retraction member from its first to its second position, whereby the first hook member 236 of the needle unit first disengages the first hook member 281 on the retraction member and thereafter slides upwardly on the ramp thereby pivoting the needle unit to its retracted position, and the second hook member 283 engages a mating structure (not shown) of the delivery device thereby locking the retraction member in its second position. To prevent the needle unit from pivoting further upwardly the second hook members 235 on the carrier (see fig. 2B) engages the housing whereby the needle unit is securely

locked in its retracted position. To prevent accidental withdrawal of the needle during use, the needle retraction member advantageously is arranged such that a given resistance has to be overcome in order to move the retraction member from its first to its second position, e.g. by using the hook member 283 to releasably lock the retraction member in its first position.

With reference to figs. 1-4 a unitary delivery device has been described in which the inserted needle is retracted before the skin-mountable delivery device is detached from the skin of the user, however, the principles of the present invention may also be implied in other configurations.

Correspondingly, with reference to figs. 5A and 5B a second embodiment of a drug delivery device will be disclosed in which a separate needle unit is releasably attached to a skin-mountable pump unit. The pump unit is adapted to be mounted on the skin of a user and used for a given number of days during which the delivery needle can be exchanged any desired number of times.

More specifically, the delivery device 100 comprises a skin-mountable pump unit 101 to which a needle unit 150 is releasable attached. The pump unit comprises a housing portion 110, in which a reservoir and expelling means are arranged, and from which a base plate portion 120 with an aperture 121 extends, the housing and the base plate portions forming a common lower mounting surface arranged on a flexible adhesive patch member 170 comprising a lower adhesive surface allowing the pump unit to be mounted on the skin of a user, the upper surface of the base plate portion and the adjacent part of the housing portion forming a receiving portion for the needle unit. When supplied to the user, the adhesive surface is advantageously covered with a peelable release liner. The reservoir is adapted to contain a liquid drug (e.g. prefilled or adapted to be filled by a user) and comprises an outlet means in the form of a protruding needle penetratable septum 145 adapted to be arranged in fluid communication with the second needle portion (see below). The expelling means (not shown) is adapted for in a situation of use to expel a drug out of the reservoir and through the skin of the subject via a hollow needle. The reservoir and expelling means may be of any suitable configuration, e.g. as disclosed with reference to figs 7A-7D.

The needle unit 150 comprises a housing 160 having a lower surface 163 and a moveable delivery needle arranged there within (see below). The needle unit is configured to be mounted on the upper surface of the base plate portion 120 and in engagement with the

housing portion by means of mating coupling means 141, 161 on the pump unit respectively the needle unit. The needle unit further comprises needle actuation means whereby the needle can be moved between an initial position in which the needle is retracted relative to the lower surface of the needle unit and an extended position in which the needle projects through the aperture 121. Preferably the needle is prevented from being moved to its extended position until the needle unit has been properly engaged with the pump unit, this to prevent unintended needle sticks. The needle may be actuated automatically when it is attached to the pump unit or manually be separate actuation means 165.

In a situation of use, the pump unit without a needle unit mounted thereto is attached to a skin surface of a user where after a needle unit is attached to the pump unit and the needle is inserted. The pump may start automatically when the needle unit is attached thereto or by manual start means (not shown). When it is deemed necessary to exchange the needle unit (e.g. after 1 or 2 days of use), the release means 162 is actuated whereby the needle firstly is retracted to a position within the needle unit and secondly detached from the pump unit. The means for moving the needle from its extended to its retracted position may have any suitable configuration, e.g. the needle may be held in its extended position by biasing means (e.g. a spring) which subsequently is released. Preferably the pump is automatically stopped by this operation just as the needle unit preferably comprises locking means for locking the needle in the retracted position after a single reciprocation of the needle from the initial position to the extended position and back to the retracted position.

As appears from the above, release means in the form of the coupling means has been operated from a first initial condition (corresponding to fig. 5A) through an intermediate condition (not shown) to a second condition (corresponding to fig. 5B), whereby operation of the release means from the first to the intermediate condition has caused the needle to be moved from an extended position to a retracted position, and operation of the release means from the intermediate to the second condition has caused release of the attaching means in the form of the coupling means from the pump unit.

The pump unit shown in fig. 5A is adapted to be mounted on the skin of a user and used for a given number of days during which the delivery needle can be exchanged any desired number of times, however, the adhesive means may be adapted for removing and remounted the device a number of times, e.g. in case it is deemed necessary to introduce a new needle at a new location. This may be accomplished by using an adhesive material

which *per se* allows the device to be removed and re-mounted a number of times, however, alternatively it may be accomplished by using "renewable" adhesive means.

More specifically, fig. 5C discloses a drug delivery device 300 of the same general type as shown in fig. 5A, i.e. a skin-mountable pump unit 301 with a thereto attached needle unit 350, however, the coupling and actuation means are not shown. The lower mounting surface of the pump unit is arranged on a flexible adhesive patch member 370 comprising a lower adhesive surface allowing the pump unit to be mounted on the skin of a user. However, in contrast to the fig. 5A embodiment, the patch member comprises a "stack" of peelable sheets 371, 372, 373 (e.g. 3 as shown). For illustrative purposes the thickness of the individual sheets and thus the stack is shown somewhat exaggerated. Each of the peelable sheets comprises an upper surface and an adhesive lower surface allowing the peelable sheets to be arranged in a stacked arrangement with their respective upper surfaces attached to the overlying adhesive surface. In the shown embodiment each of the peelable sheets as well as the sheet member directly attached to the pump unit comprises a tab 374, 375, 376 which can be gripped by the user, the tab comprising no adhesive on its lower surface. Advantageously the tabs comprise individual indication means indicating in which order they are to be used (see below). When supplied to the user, the lowermost surface is advantageously covered with a peelable release liner.

In a situation of use the release liner is removed thereby uncovering the adhesive surface of the lowermost peelable sheet (when seen from above as in fig. 5C), the adhesive surface allowing the delivery device to be attached to the skin of the user. When after a given period of time it is desirable to remove and re-mount the delivery device (which may be either concurrent with, before or after exchange of the needle) the user grips the tab of the lowermost sheet and pulls off the device from the skin surface. After this operation the same tab is used to remove the now used lowermost sheet by simply peeling it off, this operation uncovering a new "fresh" adhesive surface provided on the next sheet in the stack allowing the delivery device to be re-mounted on the skin of the user. This procedure may then be repeated corresponding to the number of peelable sheets, the "last" adhesive surface being provided by the sheet member directly attached to the pump unit. Indeed, the adhesive used and the properties of the upper surface of the individual sheet should be selected to provide safe and reliable attachment of the device to the skin of the user, prevent delaminating of the individual layers during use, yet allowing a used sheet to be peeled off easily.

As appears, the number of times the pump unit can be re-mounted on the skin surface using a fresh adhesive surface is limited to the number of adhesive surfaces provided by the stack, however, if the pump unit (or any other type of skin mountable device such as a sensor device) is intended for a relatively long period of use (either being a prefilled or user fillable unit) it may be desirable to re-mount the unit a further number of times. Addressing this problem, fig. 5D discloses a drug delivery device 400 of the same general type as shown in fig. 5C, however, in contrast to the embodiments of figs. 5A and 5C the adhesive means is not provided as part of the pump unit but is included as part of an additional base plate unit.

More specifically, the delivery device 400 comprises a base plate unit 490 having a stack of peelable sheets, a pump unit 401 and a needle unit 450. The pump unit and the needle unit are configured to be mounted on the upper surface of the base plate unit by means of mating coupling means 441, 461 on the pump unit respectively the needle unit. Alternatively the needle unit may be attached to the pump unit.

In a situation of use the delivery device of fig. 5D may be used in the same way as described above with reference to the embodiment of fig. 5C, but with the difference that the base plate unit can be exchanged a desired number of times.

Although the peelable stacks of figs. 5C and 5D are shown in combination with a device of the same type as shown in fig. 5A, it readily appears that the same stack arrangement with corresponding effect may used in combination with skin-mountable devices of any given nature, e.g. a modular arrangement as in fig. 5A in which movement of the needle is not functionally coupled to the release of a needle unit from a pump unit, a unitary delivery device comprising an externally arranged needle (e.g. connected to an infusion set) or a sensor device either unitary of modular, just as it may also be used on devices comprising no skin-piercing members, e.g. sensor devices (unitary or modular) based on non-penetrating sensor means.

Fig. 6 shows a needle subunit 180 suitable for use as part of the needle unit 150 in which it is connected to the needle housing 160 by a hinge allowing the needle subunit to pivot corresponding to a pivoting axis defined by the hinge. More specifically, the needle comprises a needle carrier 190 having a cylindrical hinge portion 191 defining the pivoting axis, and an arm member 192 extending perpendicularly from the hinge portion in respect of the pivoting axis. On a lower surface of the arm member a biasing means is arranged in the form of a leaf spring member 195 adapted to engage a portion of the needle housing. The needle carrier

carries a needle having first and second pointed end portions 181, 182 arranged substantially corresponding to the pivoting axis respectively perpendicularly thereto. Correspondingly, the needle housing 160 comprises a first opening allowing the needle penetratable septum to be advanced into fluid communication with the first pointed needle end portion 181, and a second opening in the lower surface allowing the second pointed needle portion end portion 182 to extend therefrom. The openings may be covered by penetratable barrier means whereby the needle housing can be used for providing an enclosure for a sterile needle, e.g. corresponding to figs. 3A and 3B. When the needle unit is attached to the pump unit the protruding septum is moved into engagement with the needle, during which operation fluid communication is established between the second needle portion and the reservoir. When the needle is actuated the needle subunit is pivoted from its initial to its second position (with the first needle portion being rotated corresponding to the pivoting axis), the first pointed needle end thereby being moved through the second opening in the needle housing and the aperture in the base plate portion.

In the above-described embodiments a drug delivery device has been described comprising a reservoir, however, for better illustrating the principles of the present invention, the means for expelling a drug from the reservoir has been omitted in the figures. Such expelling means, which as the reservoir does not form part of the present invention in its basic form, may be of any type which would be suitable for arrangement within a skin-mountable drug delivery device. Further, as the needle of the present invention also may be in the form of a needle sensor, the interior of the corresponding medical device may comprise sensor means adapted to cooperate with the needle sensor.

In figs. 7A-7E examples of expelling means suitable for use with the present invention are shown schematically, however, these are merely examples, just as the shown arrangement of the individual components not necessarily are suitable for direct application in the above shown delivery devices. More specifically, fig. 7A shows a pump arrangement comprising a drug-containing cartridge 1010 forming a reservoir and having a distal closure member 1011 allowing a needle to be connected, and a piston 1015 slidingly arranged there within, a flexible toothed piston rod 1020 (for example as disclosed in US patent 6,302,869), an electric motor 1030 which via a worm-gear arrangement 1031 drives the piston rod to expel drug from the cartridge, the motor being controlled by control means 1040 and the energy for the control means and the motor being provided by a battery 1050. The pump may be activated when the needle is inserted (by means not shown) or by separate user-actuatable means (not shown) after the inserter has been detached form the delivery device.

Fig. 7B shows a pump arrangement comprising a drug-containing cartridge 1110 having distal and proximal closure members 1111, 1112, and a piston 1115 slidingly arranged there within, gas generating means 1120 in fluid communication with the interior of the cartridge via conduit 1121 for driving the piston to expel drug from the cartridge, the gas generating means being controlled by control means 1140 and the energy for the control means and the gas generation being provided by a battery 1150. The pump may be activated as indicated above. A detailed disclosure of such gas generating means for a drug delivery device can be found in e.g. US patent 5,858,001.

Fig. 7C shows a pump arrangement comprising a drug-containing cartridge 1210 having distal and proximal closure members 1211, 1212, and a piston slidingly 1215 arranged there within, an osmotic engine 1220 in fluid communication with the interior of the cartridge via conduit 1221 for driving the piston to expel drug from the cartridge. The osmotic engine comprises a first rigid reservoir 1225 containing a salt-solution and a second collapsible reservoir 1226 containing water, the two reservoirs being separated by a semi-permeable membrane 1227. When supplied to the user, the fluid connection 1228 between the second reservoir and the membrane is closed by a user-severable membrane (e.g. a weak weld) which, when severed, will allow the osmotic process to start as water is drawn from the second reservoir through the membrane and into the first reservoir. The pump may be activated as indicated above. A detailed disclosure of the osmotic drive principle can be found in e.g. US patent 5,169,390.

Fig. 7D shows a pump arrangement comprising a drug-containing flexible reservoir 1310 arranged within a rigid fluid-filled secondary reservoir 1311 in fluid communication with a primary reservoir 1320 through a conduit 1330 comprising a flow restrictor 1331. The primary reservoir is in the form of a cartridge with a moveable piston 1321 and contains a viscous drive fluid. A spring 1340 is arranged to act on the piston to drive fluid from the first to the second reservoir thereby expelling drug from the flexible reservoir when the latter is connected to an infusion needle (not shown). The flow rate will be determined by the pressure generated by the spring in the drive fluid, the viscosity of the drive fluid and the flow resistance in the flow restrictor (i.e. bleeding hole principle). The pump may be activated by straining the spring or by releasing a pre-stressed spring, either when the needle is inserted (by means not shown) or by separate user-actuatable means (not shown) after the inserter has been detached form the delivery device. An example of this principle used for drug infusion is

known from DE 25 52 446. In an alternative configuration, the drug reservoir may be pressurized directly to expel the drug via a flow restrictor, e.g. as disclosed in US patent 6,074,369.

Fig. 7E shows a pump arrangement comprising a membrane pump 1430 having an outlet 1431 and control means 1440 for controlling the pump, the energy for the control means and the pump being provided by a battery 1450. The membrane pump is (in a situation of use) connected to a reservoir 1410 from which drug is sucked through the pump and expelled through the outlet. The reservoir may be provided with venting means or it may be in the form of a flexible, collapsible reservoir whereby venting means can be dispensed with. The pump may be activated when the needle is inserted (by means not shown) or by separate user-actuatable means (not shown) after the inserter has been detached form the delivery device.

In alternative embodiments (not shown) the first needle portion may be in the form of a (relatively soft) infusion cannula (e.g. a Teflon ® cannula) and a therethrough arranged removable insertion needle. This type of cannula needle arrangement is well known from so-called infusion sets, such infusion sets typically being used to provide an infusion site in combination with (durable) infusion pumps.

In the above description of the preferred embodiments, the different structures and means providing the described functionality for the different components have been described to a degree to which the concept of the present invention will be apparent to the skilled reader. The detailed construction and specification for the different components are considered the object of a normal design procedure performed by the skilled person along the lines set out in the present specification.

*****

EMBODIMENTS OF THE INVENTION

1. A needle device (250, 150), comprising:
- a lower surface adapted for application towards the skin of a subject,
- attaching means (270, 161) for securing the lower surface relative to the skin,
- a needle having a pointed end (213, 182) adapted to penetrate the skin of the subject,
- the needle being mounted for movement between an extended position in which the needle projects relative to the lower surface and a retracted position in which the needle is retracted relative to the lower surface,
- release means (175, 162) operatable from a first condition through an intermediate condition to a second condition,
- whereby operation of the release means from the first to the intermediate condition causes the needle to be moved from the extended position to the retracted position, and operation of the release means from the intermediate to the second condition causes release of the attaching means.

2. A needle device as defined in embodiment 1, wherein the lower surface is a mounting surface adapted for application against the skin of a subject.

3. A needle device as defined in embodiment 1, wherein the lower surface is a mounting surface adapted for application against the skin of a subject, the attaching means being adhesive means (270) provided on the mounting surface.

4. A needle device as defined in embodiment 3, wherein the release means comprises gripping means (275) connected to a peripheral portion of the mounting surface, the gripping means being operatable between a first condition through an intermediate condition to a second condition,
- whereby operation of the gripping means from the first to the intermediate condition causes the needle to be moved from the extended position to the retracted position, and operation of the gripping means from the intermediate to the second condition causes the mounting surface to be pulled off the skin of the subject.

5. A needle device as defined in embodiment 4, wherein the release means comprises needle retraction means (280) operatable between a first position in which the needle projects relative to the lower surface and a second position in which the needle is retracted rela-

tive to the lower surface, the needle retraction means being moved between its first and second positions when the gripping means is operated from the first to the intermediate condition.

6. A needle device as defined in embodiment 5, wherein:

- the needle retraction means is operatable connected to the gripping means such that the needle retraction means is moved between its first and second positions when the gripping means is operated from the first to the intermediate condition, and wherein
- the needle device is pulled off the skin of the subject when the gripping means is operated from its intermediate condition to its second condition.

7. A needle device as defined in embodiment 5 or 6, wherein the gripping means and the needle retraction means are operatable connected by an intermediate member (277) allowing movement of the gripping means to be transferred to the needle retraction member.

8. A needle device as defined in any of embodiments 4-7, wherein the attaching means comprises a sheet member (270) having an upper surface connected to the lower surface of the needle device, and a lower adhesive surface, the gripping means being connected to the sheet member.

9. A needle device as defined in embodiment 8, wherein the gripping means comprises a tab (276) formed integrally with the sheet member.

10. A needle device as defined in any of the previous embodiments, wherein the needle is a hollow delivery needle (210), the needle device further comprising:

- a housing (201) comprising the lower surface,
- a reservoir adapted to contain a liquid drug and comprising an outlet means (261) allowing the needle to be arranged in fluid communication with an interior of the reservoir, and
- expelling means for, in a situation of use, expelling a drug out of the reservoir and through the skin of the subject via the needle.

11. A needle device as defined in any of the previous embodiments, wherein the needle is mounted for movement between an initial position in which the needle is retracted relative to the lower surface and the extended position in which the needle projects relative to the lower surface.

12. A needle device as defined in embodiment 11, comprising locking means (283) for locking the needle in the retracted position after a single reciprocation of the needle from the initial position to the extended position and to the retracted position.

13. A needle device as defined in embodiment 1, wherein the needle is a hollow delivery needle (181, 182), in combination with a pump unit (101) comprising:

- a mounting surface adapted for application against the skin of a subject,
- a reservoir adapted to contain a liquid drug and comprising an outlet means allowing the needle to be arranged in fluid communication with an interior of the reservoir,
- expelling means for, in a situation of use, expelling a drug out of the reservoir and through the skin of the subject via the needle,
- wherein the attaching means (141, 161) is adapted for securing the needle device to the pump unit and thereby relative to the skin of the subject, and
- whereby operation of the release means from the first to the intermediate condition causes the needle to be moved from the extended position to the retracted position, and operation of the release means from the intermediate to the second condition causes release of needle device from the pump unit.

14. A combination device as defined in embodiment 13, wherein the needle is mounted for movement between an initial position in which the needle is retracted relative to the lower surface and the extended position in which the needle projects relative to the lower surface.

15. A combination device as defined in embodiment 14, wherein the needle is moved from its initial to its extended position when the needle device is secured to the pump unit.

16. A needle device as defined in any of embodiments 13-14, comprising locking means for locking the needle in the retracted position after a single reciprocation of the needle from the initial position to the extended position and to the retracted position.

17. A combination device as defined in any of embodiments 13-16, wherein the mounting surface comprises an aperture (121), the needle device being secured relative to the mounting surface with the needle in register with the aperture, the needle being adapted to extend through the aperture in its extended position.

18. A combination device as defined in any of embodiments 13-17, wherein a receiving portion of the pump unit and a corresponding portion of the needle device comprise the attaching means in the form of mating, releasable coupling means (141, 162) allowing the needle unit to be secured to the pump unit.

19. A combination device as defined in any of embodiments 13-18, wherein the mounting surface comprises mounting means (170) having an adhesive surface.

20. A needle (450) device as defined in embodiment 1, wherein the needle is a hollow delivery needle (181, 182), in combination with a pump unit (401) and a base plate unit (490), the base plate unit comprising:

- an upper surface and a lower mounting surface adapted for application against the skin of a subject, the mounting surface comprising mounting means (470) having an adhesive surface, the pump unit comprising:
- a reservoir adapted to contain a liquid drug and comprising an outlet means allowing the needle to be arranged in fluid communication with an interior of the reservoir,
- expelling means for, in a situation of use, expelling a drug out of the reservoir and through the skin of the subject via the needle,
- the pump unit and the base plate unit comprising mating, releasable coupling means (441) allowing the pump unit to be secured to the base plate unit,
- wherein the attaching means (461) is adapted for securing the needle device to the pump unit and/or the base plate unit and thereby relative to the skin of the subject, and
- whereby operation of the release means from the first to the intermediate condition causes the needle to be moved from the extended position to the retracted position, and operation of the release means from the intermediate to the second condition causes release of needle device from the pump unit.

21. A combination device (300, 400) as defined in embodiment 19 or 20, further comprising a first peelable sheet (371) having an upper surface and an adhesive lower surface, the upper surface being adapted for peelable attachment to the adhesive surface of the mounting surface.

22. A needle or combination device as defined in embodiment 21, comprising at least one further peelable sheet (372, 373), each further peelable sheet comprising an upper surface and an adhesive lower surface, the first and the further peelable sheets being arranged

in a stacked arrangement with their respective upper surfaces attached to the overlying adhesive surface.

ABSTRACT

The invention relates to needle-like members adapted for insertion at a selected site within the body of a subject, the invention providing a needle device comprising a lower surface adapted for application towards the skin of a subject, attaching means for securing the lower surface relative to the skin, and a needle having a pointed end adapted to penetrate the skin of the subject. The needle is mounted for movement between an extended position in which the needle projects relative to the lower surface and a retracted position in which the needle is retracted relative to the lower surface. The needle device further comprises release means which can be operated from a first condition through an intermediate condition to a second condition, whereby operation of the release means from the first to the intermediate condition causes the needle to be moved from the extended position to the retracted position, and operation of the release means from the intermediate to the second condition causes release of the attaching means.

Fig. 1B

Fig. 1A

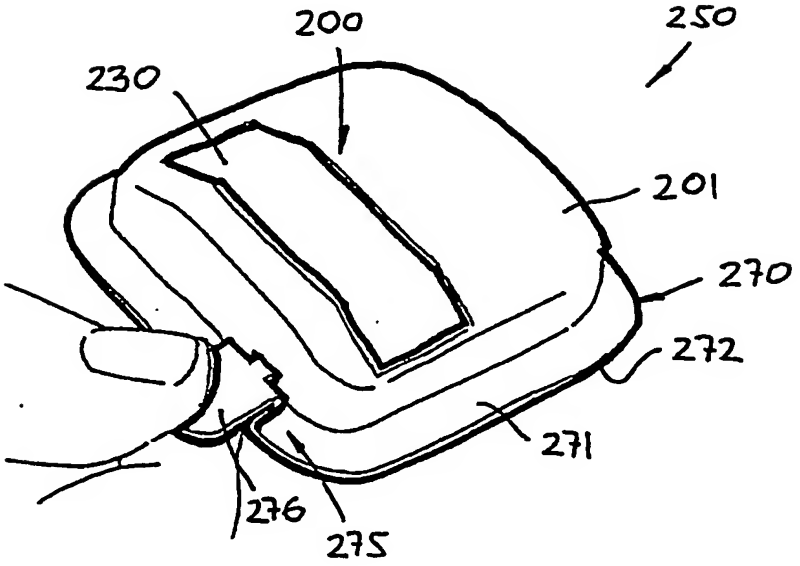


Fig. 1B

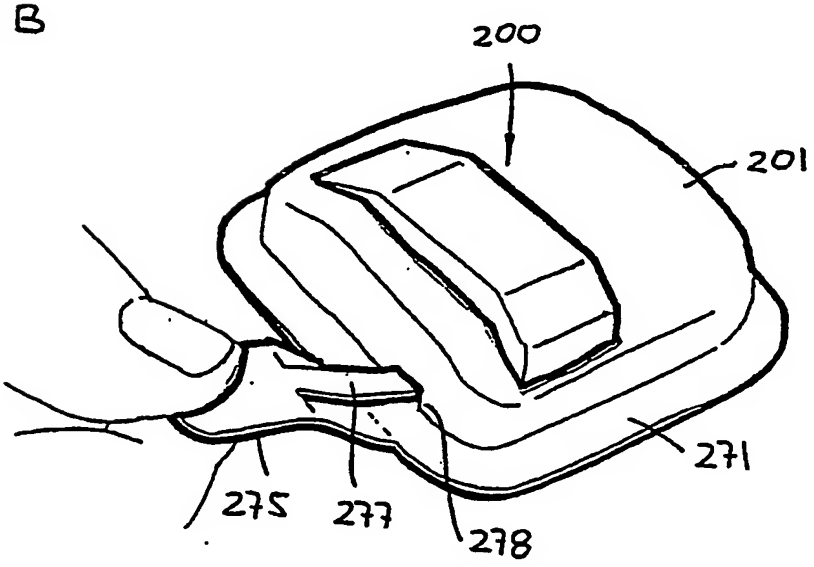


Fig. 2A

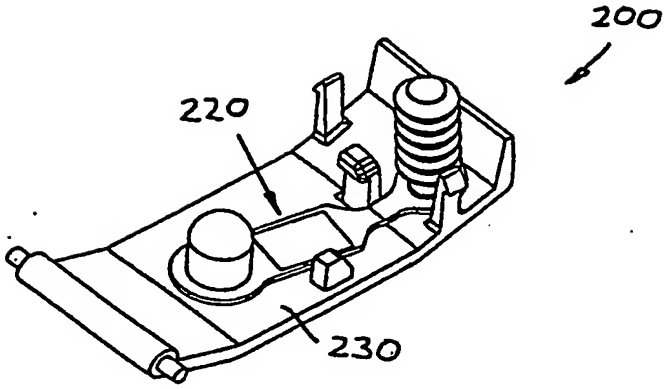

200
220
230

Fig. 2B

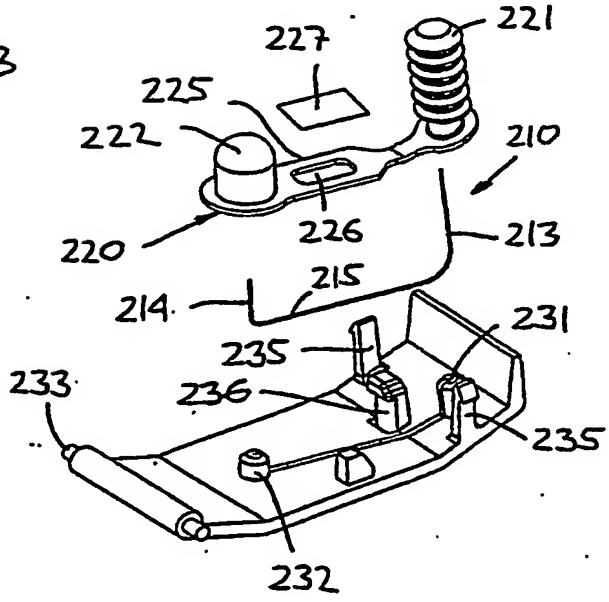

227
221
225
222
210
220
226
213
215
214
231
235
233
236
235
232

Fig. 3A

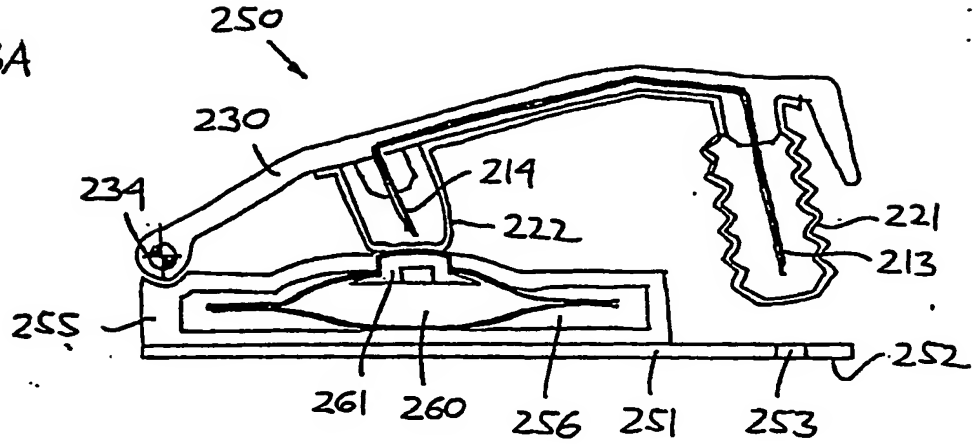

250
230
234
214
222
221
213
255
252
261
260
256
251
253

Fig. 3B

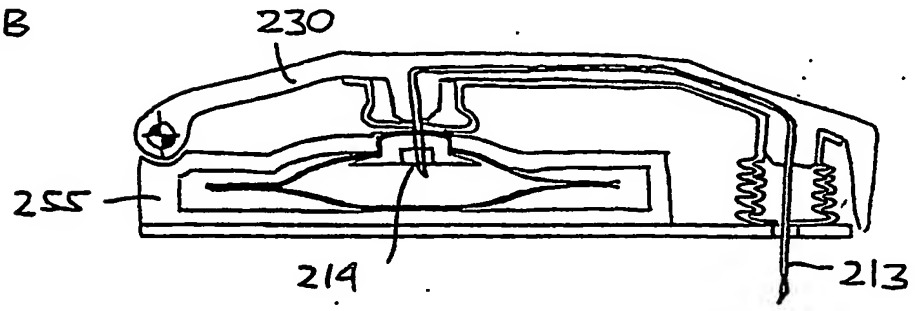

230
255
214
213

Fig. 4A

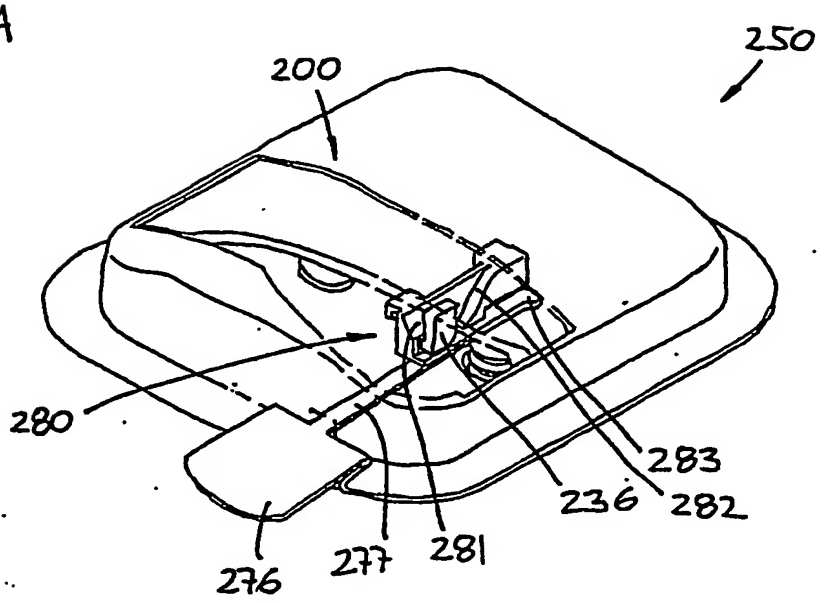

250
200
280
283
236
282
276
277
281

Fig. 4B

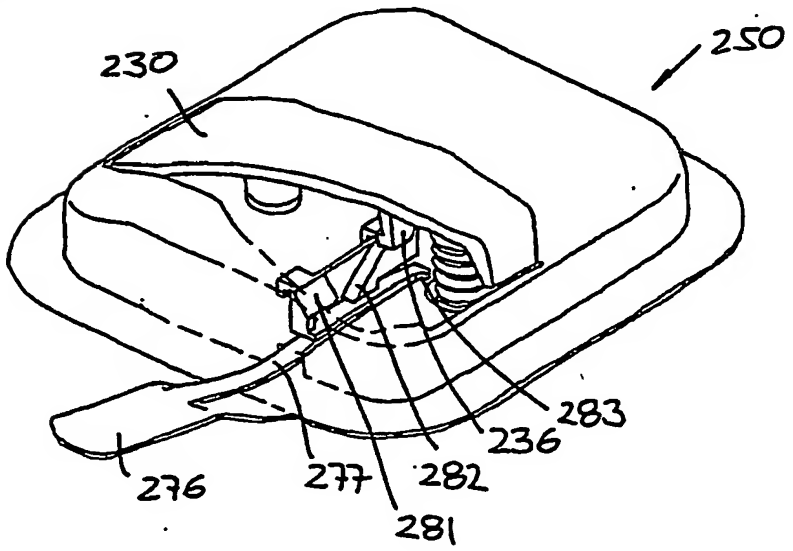

250
230
283
236
276
277
282
281

Fig. 5A

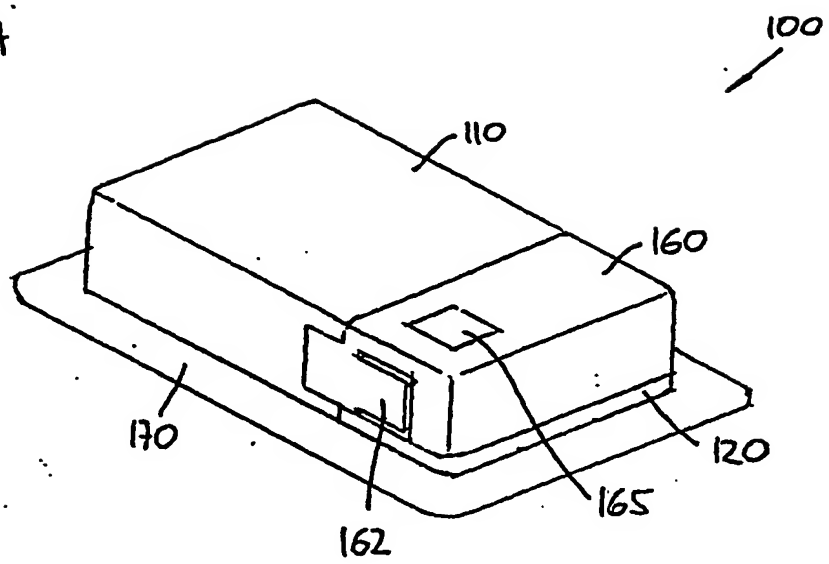

100
110
160
170
120
165
162

Fig. 5B

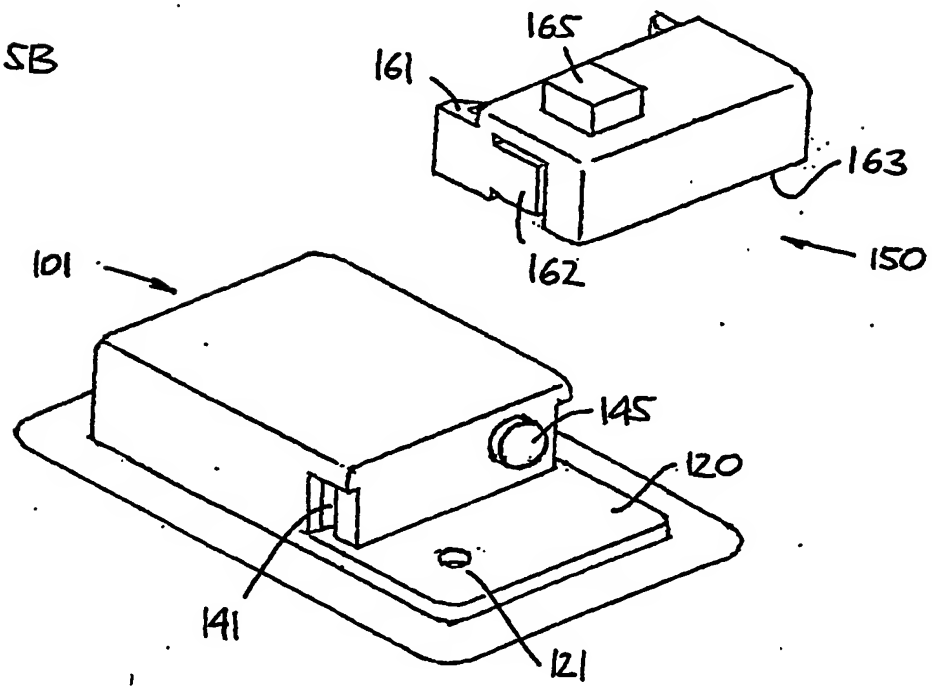

165
161
163
150
162
101
145
120
141
121

Fig. 5C

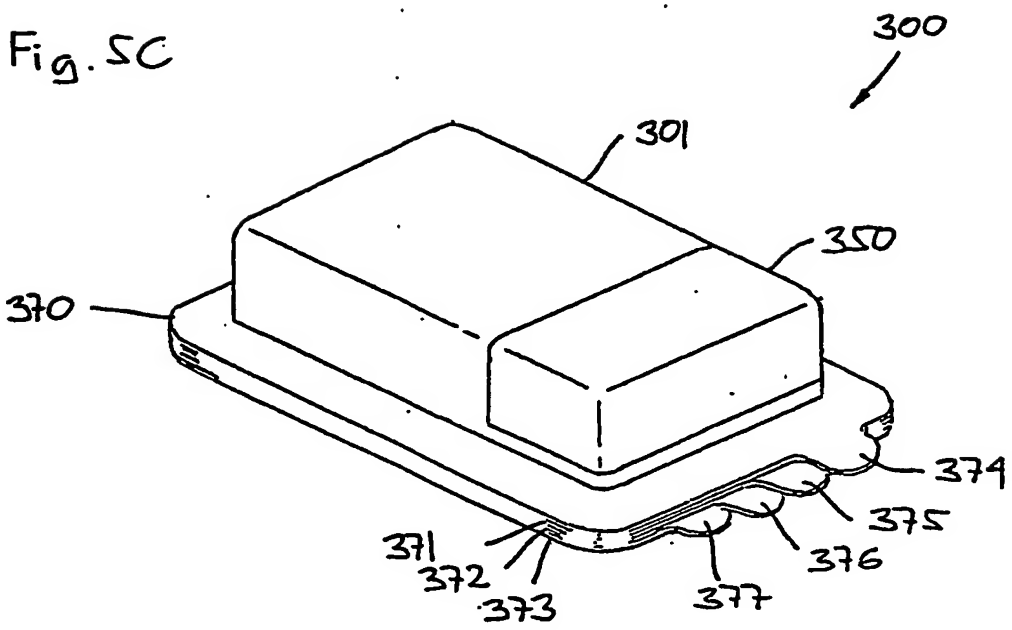

300
301
350
370
374
375
376
371
372
373
377

Fig. 5D

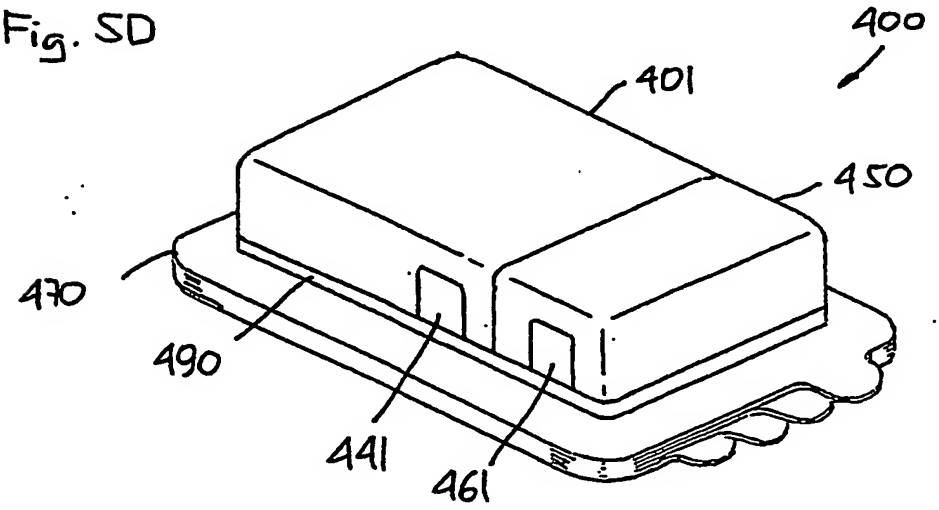

400
401
450
470
490
441
461

Fig. 6

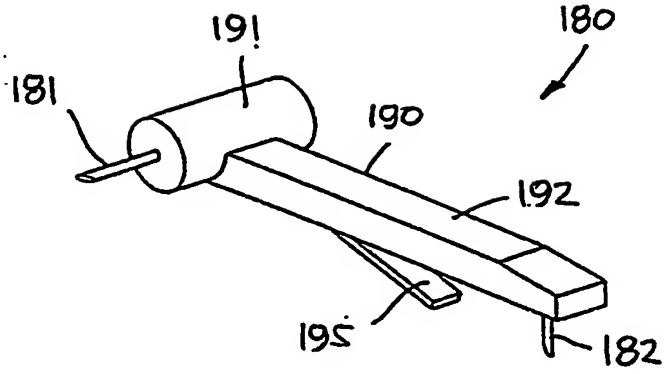


Fig. 7A

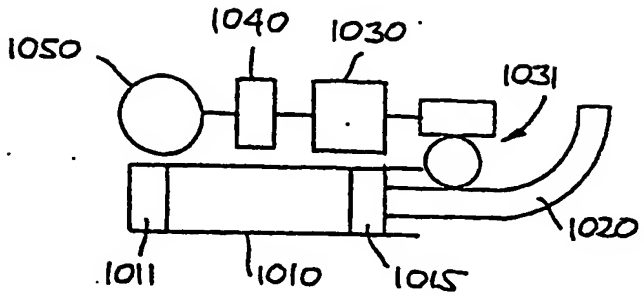


Fig. 7B

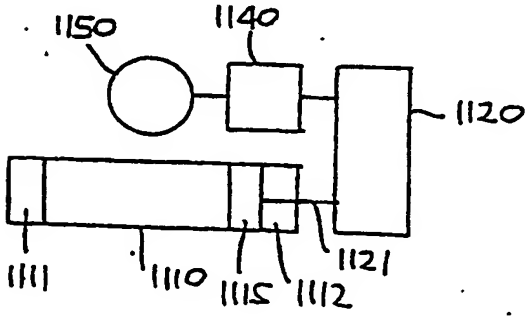


Fig. 7C

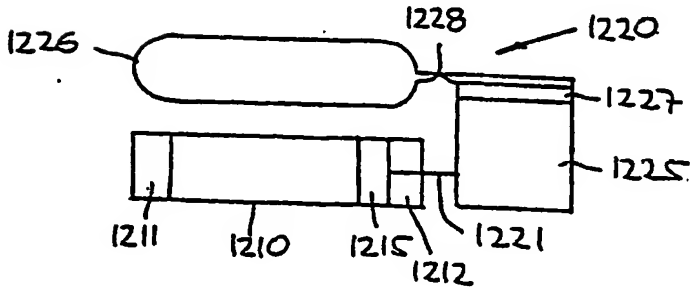


Fig. 7D

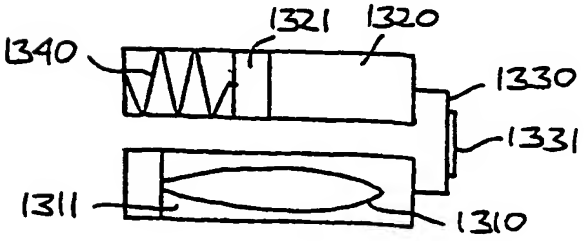
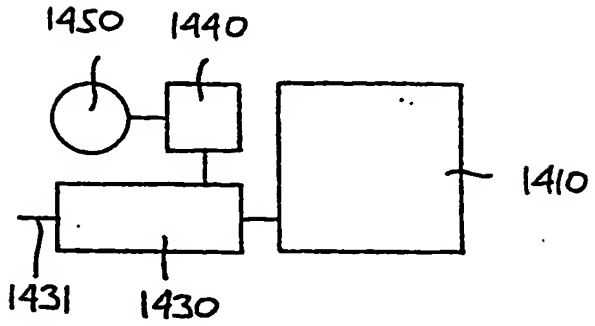


Fig. 7E



This Page is Inserted by IFW Indexing and Scanning Operations and is not part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☑ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.
As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.